

### **Remarks**

Initially, applicant's attorney notes that, as required by Rule 1.121, the claims of the above-identified application to be amended by this Amendment have been presented above with amendments in clean form, as well as in the final pages of this Amendment in marked-up form to show the changes made.

Applicant's attorney thanks the Examiner for the Office Action issued on December 16, 2002 in connection with the present application. More particularly, the sole independent claim (i.e., Claim 1) has been rejected based upon a single primary reference (i.e., de la Torre U.S. Patent No. 5,368,602), while the remaining claims (i.e., dependent Claims 2-15) have been rejected based upon the de la Torre '602 Patent in combination with one or more secondary references (i.e., Mulhauser et al. U.S. Patent No. 5,766,246; Kugel U.S. Patent No. 5,634,931; and Kugel U.S. Patent No. Des. 416,327).

By the foregoing amendments, independent Claim 1 has been amended to emphasize and clarify certain novel features of the present invention. More particularly, amended Claim 1 recites a prosthetic mesh system adapted for implantation in a body. According to amended Claim 1, the mesh system includes a biocompatible mesh layer which is flexible such that the mesh layer has a generally flat shape when it is in a first condition and a generally collapsed shape when it is in a second condition. Amended Claim 1 also recites that the mesh layer has at least one ridge formed integrally therewith and projecting therefrom in a direction substantially perpendicular to the mesh layer when the mesh layer is in its first condition. In accordance with amended Claim 1, the ridge is sized and shaped so as to facilitate the movement of the mesh layer from its collapsed shape to its flat shape. As recited in

amended Claim 1, the mesh layer in the location of the ridge has a rigidity **which is not greater than** the rigidity of the rest of the mesh layer. In this manner, the mesh layer can conform to anatomical structures adjacent to a hernia defect without having certain portions with rigidity greater than the rest of the mesh layer (see page 6, lines 9-12, of the present application).

It is respectfully submitted that none of the references relied upon by the Examiner in the Office Action (i.e., de la Torre U.S. Patent No. 5,368,602; Mulhauser et al. U.S. Patent No. 5,766,246; Kugel U.S. Patent No. 5,634,931; and Kugel U.S. Patent No. Des. 416,327) discloses or suggests, whether considered individually or collectively, the novel features of the present invention recited in amended Claim 1. For instance, the de la Torre '602 Patent discloses a surgical mesh having a patch (24) of **flexible** mesh material and a **semi-rigid** member (26) formed with the patch (24). More particularly, as specified in the de la Torre '602 Patent, the semi-rigid member (26) is **less flexible** (i.e., **more rigid**) than the mesh material so as to enable the manipulation and controlled positioning of the entire mesh area of the patch (see, for instance, column 4, lines 1-4, of the de la Torre '602 Patent). In such circumstances, there is no disclosure or suggestion in the de la Torre '602 Patent of a mesh layer having in the location of the ridge a rigidity **which is not greater than** the rigidity of the rest of the mesh layer, as recited in amended Claim 1. In fact, the de la Torre '602 Patent teaches away from such a concept by requiring a **semi-rigid** member that is **less flexible** (i.e., **more rigid**) than the rest of the mesh.

With respect to the Mulhauser et al. '246 Patent, it discloses an implantable prosthesis having a **flexible** mesh layer (12) and a **semi-rigid** frame or ring (14). In such circumstances, like the de la Torre '602 Patent, the Mulhauser et al. '246

Patent teaches away from the concept of providing a mesh layer having in the location of the ridge a rigidity **which is not greater than** the rigidity of the rest of the mesh layer, as recited in amended Claim 1.

The remaining secondary references (i.e., the Kugel '931 Utility Patent and the Kugel '327 Design Patent) also fail to disclose or suggest the mesh system recited in amended Claim 1. As acknowledged in the Office Action, these secondary references do not disclose or suggest the novel features originally recited in Claim 1 (e.g., a ridge integrally formed with the mesh layer). In addition, there is no disclosure or suggestion in these secondary references of a mesh layer having in the location of the ridge a rigidity **which is not greater than** the rigidity of the rest of the mesh layer, as recited in amended Claim 1.

In the foregoing circumstances, it is respectfully submitted that the mesh system recited in amended Claim 1 is patentably distinguishable over the references cited by the Examiner in the Office Action, whether they are considered individually or collectively. Accordingly, it is believed that amended Claim 1 is in condition for allowance together with the claims depending therefrom (i.e., Claims 2-15).

While Claims 11 and 12 are believed to be in condition for allowance due to their dependency from amended independent Claim 1, it is noted that these claims recite additional novel features of the present invention. For instance, Claim 11 recites that each of the ridges has a ring shape, while Claim 12 recites that the ridges are arranged in a concentric manner. In rejecting Claims 11 and 12, the Examiner cited the Kugel '327 Design Patent as disclosing these features. While the Kugel '327 Design Patent shows ring-shaped concentric structures, it fails to disclose exactly what they are. As noted on the face of the Kugel '327 Design Patent, this patent derived from the

Kugel '931 Utility Patent, which discloses a hernia mesh patch basically identical to the one disclosed in the Kugel '327 Design Patent. More particularly, the hernia patch disclosed in the Kugel '931 Utility Patent<sup>1</sup> has a spring-like ring mounted within an interior pouch which is formed between two mesh layers. As a result, the ring-shaped concentric structures illustrated in the Kugel '327 Design Patent are likely to be the ring and attaching or stitching patterns for attaching the mesh layers to one another and/or for forming the interior pouch, rather than ring-shaped concentric ridges as indicated by the Examiner in the Office Action. In the foregoing circumstances, it is respectfully submitted that the features recited in Claims 11 and 12 (i.e., ridges having a ring shape and being arranged in a concentric manner) are not disclosed in, or suggested by, the Kugel '327 Design Patent, whether it is considered alone or in combination with the remaining references relied upon by the Examiner in the Office Action (i.e., the de la Torre '602 Patent, the Mulhauser et al. '246 Patent and the Kugel '931 Utility Patent).

New Claims 16-20 have been added. More particularly, new independent Claim 16 recites the subject matter of amended Claim 1 in a slightly different way. In such circumstances, for the reasons discussed above, it is respectfully submitted that the device recited in Claim 16 is patentably distinguishable over the references cited in the Office Action and that Claim 16 is therefore in condition for allowance. Because the remaining new claims (i.e., Claims 17-20) depend from Claim 16, they are believed to be in condition for allowance.

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<sup>1</sup> Based upon the fact that the Kugel '931 Utility Patent was not applied to Claims 11 and 12, it appears that the Examiner has acknowledged that this patent does not disclose or suggest the features recited in Claims 11 and 12 (i.e., ridges having a ring shape and being arranged in a concentric manner).

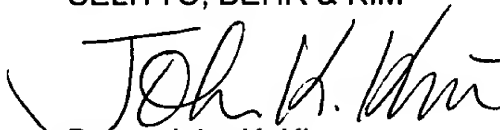
For the sake of good order, applicant's attorney notes that a Supplemental Information Disclosure Statement ("SIDS") was filed two days prior to the issuance of the Office Action (i.e., on December 14, 2002). In such circumstances, the Office Action fails to acknowledge that the references cited in the SIDS were considered and made of record by the Examiner in connection with this application. Accordingly, applicant and his attorney respectfully request that such action be undertaken.

In view of the foregoing amendments and the above comments, it is believed that all of the Examiner's prior art rejections contained in the Office Action have been obviated. Accordingly, reexamination and allowance of Claims 1-15 and examination and allowance of new Claim 16-20 are respectfully requested. If, however, such action cannot be taken, the Examiner is cordially invited to contact applicant's attorney at his number below in order that any outstanding issue may be resolved without the issuance of a further Office Action.

No fees are believed to be due in connection with the submission of this Amendment. If any such fees are due, the Examiner is hereby authorized to charge them to Deposit Account No. 19-1218.

Respectfully submitted,

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## **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

### **In the Claims**

Claims 1 and 3 has been amended as follows.

1. (Amended) A prosthetic mesh system adapted for implantation in a body, comprising a biocompatible mesh layer, said mesh layer being flexible such that said mesh layer has a generally flat shape when it is in a first condition and a generally collapsed shape when it is in a second condition, said mesh layer having at least one ridge formed integrally therewith and projecting therefrom in a direction substantially perpendicular to said mesh layer when said mesh layer is in said first condition, said at least one ridge being sized and shaped so as to facilitate the movement of said mesh layer from its said collapsed shape to its said flat shape, and said mesh layer in the location of said at least one ridge having a rigidity which is not greater than the rigidity of the rest of said mesh layer.

3. (Amended) The prosthetic mesh system of Claim 2, wherein said at least one ridge is sized and shaped such that said mesh layer is expandable from its said collapsed shape[d] to its said flat shape after being implanted in a body.